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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,713 06/13/00 BUSSEMAKERS

M 1619.0020001

EXAMINER

HM12/0821

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DAVIS, N

ART UNIT

PAPER NUMBER

1642

14

DATE MAILED:

08/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Office Action Summary**

Application No.

09/402,713

Applicant(s)

BUSSEMAKERS, MARION J. G.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a nucleic acid molecule encoding prostate cancer antigen 3, a kit, vector, host cell, and a method of detecting PCA3 nucleic acid.

Group II, claim(s) 15-16, drawn to a PCA3 polypeptide.

Group III, claim(s) 17-19, drawn to an antibody having specific binding affinity to the PCA3 polypeptide and a method of detecting PCA3 in a sample.

Group IV, claim(s) 20, drawn to a hybridoma, which produces the monoclonal antibody to PCA3 of claim 17.

Group V, claim(s) 21, drawn to a method of treating prostate cancer using an antibody.

Group VI, claim(s) 22, drawn to a method of treating prostate cancer using antisense PCA3 nucleic acid.

Group VII, claim(s) 23, drawn to a method of diagnosis for the presence or predisposition to develop prostate cancer.

2. The inventions have been found by the examiner to have no special technical feature that defined a contribution over the prior art because Bussemakers, et al., (1996) teach DD3 (PCA3) as a new prostate specific marker, which is overexpressed in prostate cancer. Since the inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and lack unity of invention.

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3. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is drawn to a PCA3 nucleic acid. The invention of Group II is drawn to a PCA3 polypeptide. The invention of Group III is drawn to an antibody to PCA3. The invention of Group IV is drawn to a hybridoma that produces an antibody to PCA3. The invention of Group V is drawn to a method of treatment using a PCA3 antibody. The invention of Group VI is drawn to a method of treatment using antisense PCA3. The invention of Group VII is drawn to a method of diagnosis by detection of PCA3.

4. The Inventions of Groups I-IV (products) and V-VII (methods) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-IV may be used for a number of different processes that are very much unrelated. For example, the PCA3 antibody of Group III may not only be used in the method of Group V, but may also be used for immunopurification. Likewise, the protein of Group II may be used for affinity purification of antibodies and the nucleic acid of Group I may be used in a vaccine.

5. The products of Groups I-IV are drawn to structurally and functionally different molecules with different immunological properties, each invention requires different reagents and steps to make and characterize it.

6. The methods of Groups I and III relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.  
August 20, 2001

  
**GEETHA P. BANSAL**  
**PRIMARY EXAMINER**